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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,952	06/25/2003	Peter Lyon Harris	292-PDD-99-20-CON-[70P2]	3111

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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/603,952	Applicant(s) HARRIS ET AL.	
	Examiner David H. Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-22 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-22, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claim 22 is objected to because of the following informalities: In claim 22, line 3, “polytetrafluoroethylene” is misspelled. Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ehrenfeld, US 5,156,619, which discusses a prior art example including a generally uniform surface (column 1, line 65, to column 2, line 5) and a first nominal or minimal inner diameter (column 1, lines 51-57; Figures 1-3) that tapers to a smaller second nominal or minimal inner diameter (column 2, lines 17-20) adjacent the end formation **23** (column 2, lines 6-9). Regarding claim 2 and others, the crimps **16** impart convexity to portions of the “toe” region, and the generally circular cylindrical geometry of segment **12** (Figure 1) likewise defines a convexity. Regarding claim 7 and others, a second end formation would have been inherent from column 1, lines 5-8.

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Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrenfeld, US 5,156,619. Regarding claim 6, diameters within the particular ranges would have been obvious from the ranges specified by Ehrenfeld (column 1, lines 54-57; column 4, lines 10-15) and from the diversity of blood vessel sizes known to the ordinary practitioner. Regarding claim 15 and others, PTFE would have been an obvious alternative thread or coating in view of column 1, lines 13-20.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson, US 4,530,113. Forming the shunt **10** of Figure 6 without the pleats or corrugations **12** (so as to create a *constant* inner dimension) would have been an obvious step backward (column 6, lines 49-59) in order to simplify manufacture. The inner arc lengths and diameters along the ends **44** are variable by virtue of the oblique cut (column 7, lines 9-11), which also defines an elongate, non-circular opening of greater area than that of a cross-section transverse to a central axis along an intermediate portion of the shunt **10**. Attention is also directed to column 6, line 32.

Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pintauro et al., US 5,782,916. Figure 13 illustrates an end formation **114** capable of connection to a blood vessel opening (column 3, lines 58-64; column 4, lines 35-43; column 9, line 8 et seq.) and a first diameter portion surrounding the valve **124** and tapering to a smaller second diameter portion (column 7, lines 66-67) adjacent the end formation **114**, which defines openings having non-circular perimeters (Figures 1, 8, 10, 14, and 15; column 8, lines 5 and 14-18; column 4, lines 8-20; etc.). Regarding claim 2, a second transverse diameter may be defined near the reinforcing ring **17** or **117** (Figures 1, 8, 10, and 13), and the *internal* toe surface

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is concave (Figure 13). Regarding claim 21, the second engagement may be viewed as involving anchor **116**, with valve **124** defining a lesser third diameter portion.

Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pintauro et al., US 5,782,916. Regarding claim 6, the particular dimensions would have been within the realm of obvious variants in view of the diversity of pertinent anatomical dimensions found in the animal kingdom and in view of column 4, lines 17-20 and 32-34; column 8, lines 3-6 and 38-44; and column 8, line 49 et seq. Regarding claim 15 and others, PTFE would have been immediately obvious from column 8, lines 45-48.

The Applicant's remarks have been considered. The examiner acknowledges that the Caro document says little or nothing about the inner tubular dimensions. The rejections based upon Caro have thus been withdrawn in favor of those presented above (MPEP § 706.02, section I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**